



I-010697-X-0149-CE

U. S. Fish & Wildlife Service  
Aquatic Animal Drug Approval Partnership Program  
Attention: David Erdahl, Ph.D.  
Branch Chief, AADAP  
4050 Bridger Canyon Road  
Bozeman, MT 59715

Re: Claim for a categorical exclusion for investigational use of AQUAFLOr (florfenicol) medicated feed in freshwater and marine finfish

Dear Dr. Erdahl:

Your June 18, 2013, claim for a categorical exclusion (CE), meets the criteria for CE under 21 CFR 25.33(e) for the investigational use of AQUAFLOr (florfenicol) medicated feed. The drug is proposed for investigational use in freshwater and marine finfish for treatment of bacterial diseases. Your submission also adequately states that to your knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment (21 CFR 25.21). We agree that the proposed uses of this drug as described above fall within the claimed CE and we are not aware of any extraordinary circumstances. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required.

Your investigators are responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES); as well as any applicable ground-water pollution requirements, for all investigational sites covered under this INAD. They must also comply with all drug use reporting requirements specified in 40 CFR 451.3(a) for concentrated aquatic animal production facilities. In addition, this CE from the preparation of an EA and an EIS does not relieve you or your investigators of the responsibility for determining and meeting all other Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of investigational drugs.

Because several environmental assessments have been prepared recently for AQUAFLOr that address its use in aquaculture, you no longer need to claim a CE or notify the Environmental Safety Team if the scope of your investigation changes (e.g., if additional facilities will treat fish, if the protocol changes in ways which could result in increased environmental exposure, etc.) under this INAD or you request an amended authorization under this INAD.

This CE only addresses the investigational use of your product. Before submitting your administrative new animal drug application (NADA), a separate request for a CE or preparation of an EA for the NADA is required.

For all categorical exclusion claims under 21 CFR 25.33, we ask that you include relevant drug information to allow CVM to properly evaluate extraordinary circumstances (21 CFR 25.21), and to insure that we can properly document the categorical exclusion. The following should be included, if known: the target species, indication(s), dose, duration, frequency, route of administration, how it will be dispensed (e.g., prescription, over-the-counter), established name, and trade name. Indicate whether the product is a nanomaterial and/or will be produced by recombinant DNA technology (e.g., by genetically engineered microorganisms). If any of the above information is not known at the time that the CE is submitted, this should be indicated in the submission.

If you submit correspondence relating to this letter, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Eric Silberhorn of the Environmental Safety Team by email at [eric.silberhorn@fda.hhs.gov](mailto:eric.silberhorn@fda.hhs.gov). You may also contact Dr. Holly Zahner, Leader, Environmental Safety Team via email at [holly.zahner@fda.hhs.gov](mailto:holly.zahner@fda.hhs.gov). We do not recommend trying to contact us by phone at this time because many of our phones have recently been disconnected as a result of office moves.

Sincerely,

*{see appended electronic signature page}*

Veronica N. Taylor, Ph.D.

Director, Division of Scientific Support

Office of New Animal Drug Evaluation

Center for Veterinary Medicine

**Electronic Signature  
Addendum for Submission ID**

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| <b>Signing Authority (Role)</b>     | <b>Letter Date</b> |
|-------------------------------------|--------------------|
| Veronica Taylor (Division Director) | 9/18/2013          |

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